General

Guideline Title

ACR Appropriateness Criteria® management of vaginal cancer.

Bibliographic Source(s)

Lee LJ, Jhingran A, Kidd E, Gaffney DK, Cardenes HR, Elshaikh MA, Erickson B, Mayr NA, Moore D, Puthawala AA, Rao GG, Small W Jr, Varia MA, Wahl AO, Wolfson AH, Yashar CM, Yuh W, Expert Panel on Radiation Oncologyâ€“Gynecology. ACR Appropriateness CriteriaÂ® management of vaginal cancer. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 11 p. [49 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Management of Vaginal Cancer

Variant 1: 52-year-old woman with remote hysterectomy for cervical dysplasia and 1- x 1.5- x 1 cm invasive SCC involving right vaginal fornix without paravaginal extension.

Treatment	Rating	Comments
Pretreatment Evaluation		
X-ray chest	6	
CT abdomen and pelvis	7	
MRI abdomen and pelvis	8	
CT chest	6	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment	Rating	Comments
FDG-PET/CT whole body	8	
Cystoscopy	4	
Definitive Treatment		
Upper vaginectomy and pelvic node dissection	6	
Brachytherapy alone	2	
EBRT alone	3	
EBRT and brachytherapy	8	
Local excision and EBRT	5	
Chemoradiotherapy (EBRT alone)	3	
Chemoradiotherapy (EBRT and brachytherapy)	8	
Following EBRT to 45 Gy, residual disease measured <5 mm in thickness		
Brachytherapy Technique		
Vaginal cylinder	8	
Interstitial implant	4	
Brachytherapy Modality		
Low-dose-rate	8	
High-dose-rate	9	
Pulsed-dose-rate	8	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: 68-year-old woman with FIGO stage II SCC of distal vagina, 3 x 3 x 4 cm in size involving suburethral area. No nodal involvement or distant disease by PET/CT.

Treatment	Rating	Comments
Definitive Treatment		
EBRT alone	3	
EBRT and brachytherapy	8	
Chemoradiotherapy (EBRT alone)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment	Rating	Comments
Chemoradiotherapy (EBRT and brachytherapy)	8	
Vulvovaginectomy with anterior exenteration	3	
Radiation Therapy Technique		
2-D RT	3	
3-D conformal RT	8	
IMRT	8	
Elective Nodal Coverage		
Pelvic nodes only	3	
Pelvic and bilateral inguinal nodes	8	
Low pelvic and bilateral inguinal nodes	6	
Superior Field Border (nodal CTV)		
L5/S1 (or bifurcation of common iliacs)	7	
L4/L5 (or bifurcation of aorta)	6	
Mid-SI joint	5	
Bottom of SI joint	3	
Residual Disease Measured 2 cm in Thickness Following EBRT to 45 Gy with Concurrent Chemotherapy		
Method of Boost		
3-D conformal	3	
IMRT	5	
Cylinder brachytherapy	2	
Interstitial brachytherapy	8	
Cumulative Delivered Dose with EBRT Boost (If Brachytherapy Not Performed)		
60–65 Gy	5	
70–75 Gy	7	
80–85 Gy	3	
Cumulative Delivered Dose with Brachytherapy Boost		
60–65 Gy	3	

Treatment	Rating	Comments
70–75 Gy	7	
80–85 Gy	7	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: 65-year-old woman with FIGO stage III SCC of the vagina with full-length involvement and pelvic sidewall extension measuring 5 x 7 x 7 cm. PET/CT shows bulky primary disease and a 2- x 3 cm external iliac lymph node but no distant metastases.

Treatment	Rating	Comments
Definitive Treatment		
EBRT alone	3	
EBRT and brachytherapy	5	
Chemoradiotherapy (EBRT alone)	5	
Chemoradiotherapy (EBRT and brachytherapy)	8	
Neoadjuvant chemotherapy followed by RT	3	
Neoadjuvant chemotherapy followed by radical surgery	2	
Exenteration with postoperative RT for close/positive margins	2	
Palliative RT	3	
Concurrent Chemotherapy		
Weekly cisplatin	8	
Bolus cisplatin and 5-FU	6	
Cisplatin and gemcitabine	3	
Weekly paclitaxel	3	
Superior Field Border (nodal CTV)		
L3/L4 (cover low para-aortics)	7	
L4/L5 (or bifurcation of aorta)	7	
L5/S1 (or bifurcation of common iliacs)	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment	Rating	Comments
After 45 Gy EBRT with Concurrent Chemotherapy, the Primary Vaginal Disease Measures 3 x 4 x 4 cm and Nodal Disease Measures 1 x 1 cm		
Boost to Pelvic Nodal Disease		
No boost	2	
Pelvic sidewall boost to 54–60 Gy with midline block	6	
Conformal nodal boost to 60–66 Gy	7	
IMRT nodal boost to 60–66 Gy	8	
Boost to Primary Vaginal Disease		
Conformal boost to vaginal CTV to 65–75 Gy	5	
IMRT boost to vaginal CTV to 65–75 Gy	7	
Interstitial brachytherapy to vaginal CTV to 70–85 Gy	8	
Vaginal cylinder brachytherapy to 70–85 Gy	1	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: 85-year-old woman with FIGO stage IVB SCC of the vagina with pelvic sidewall fixation, pain, and vaginal bleeding. PET/CT shows FDG-avid lymphadenopathy in the pelvis, inguinal nodes, and mediastinum, as well as pulmonary metastases. Karnofsky performance status is 50.

Treatment	Rating	Comments
Primary Management		
Palliative radiotherapy	8	
Palliative chemotherapy	3	
Chemoradiotherapy	3	
Palliative exenteration	1	
Best supportive care with pain management	5	
Radiation Fields		
Primary tumor volume with 2 cm margin	7	
Pelvic only	5	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment	Rating	Comments
Pelvis and involved inguinal nodes	6	
Pelvis, inguinal and para-aortic nodes	3	
Radiation Dose		
10 Gy in single fraction	4	
3.7 Gy BID for 2 days q2 weeks to 44.4 Gy	7	
30 Gy in 10 fractions	7	
50 Gy in 25 fractions	3	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction

Primary carcinoma of the vagina is a rare malignancy, representing 3% of all gynecologic cancers, and is diagnosed in an estimated 2,900 women annually in the United States. The majority of primary vaginal cancers are squamous cell carcinomas, which are frequently associated with human papillomavirus infection. Given the rarity of this disease, prospective trials of patients with vaginal cancer have not been feasible, and evidence for treatment relies on single institutional reports of clinical outcomes spanning several decades. Due to these limitations, management guidelines for vaginal cancer are currently extrapolated from reported clinical experience and prospective studies of cervical and anal cancer, given the similarities in disease etiology and desire for organ preservation.

Staging

Staging for vaginal cancer relies on the clinical evaluation, according to the Federation of Gynecology and Obstetrics (FIGO) system, which allows for chest radiographs, examination under anesthesia with bimanual and rectovaginal examination, cystoscopy and/or proctoscopy (in patients with urinary or rectal symptoms), and intravenous pyelogram to evaluate for hydronephrosis. By the FIGO system, tumors that involve the cervix or vulva are not considered vaginal cancers and are classified as cervical or vulvar primaries. As in cervical cancer staging, FIGO encourages the use of advanced imaging modalities, such as computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET), to guide therapy, although in historic series and resource-poor settings the imaging findings may not be used to determine the stage in order to preserve the FIGO system.

Given its superior soft-tissue resolution, MRI is particularly useful in delineating tumor size and extent and is more sensitive than physical examination in assessing paravaginal or parametrial involvement in patients with cervical cancer. Primary vaginal tumors are best visualized on T2-weighted imaging and appear hyperintense. Visualization of the vaginal tumor may be improved with the instillation of vaginal gel or a dry vaginal tampon, which distends the vaginal walls and allows for assessment of the tumor thickness.

PET imaging has become a standard diagnostic tool in the initial staging of cervical cancer and for post-treatment surveillance. PET has shown a similar applicability for vaginal cancer, as its sensitivity for detecting primary vaginal tumors and involved inguinal or pelvic lymph nodes is greater than that of CT alone. CT may be used to delineate the disease extent and evaluate for nodal and distant metastatic spread, although its sensitivity is modest compared to MRI and PET. CT is primarily used for 3-dimensional (3-D) conformal treatment planning for radiotherapy delivery (see Variant 1, above).

Treatment of Early-Stage Vaginal Cancer

Early-stage vaginal cancer is defined as an invasive disease confined to the vaginal mucosa and/or paravaginal tissues (FIGO stages I–II). The treatment approaches for early-stage disease include surgical resection or definitive radiotherapy. The advantages of surgery are the preservation of ovarian and sexual function and elimination of the risk of radiation-associated malignancy. Lesions that are well-circumscribed in the upper vagina may be amenable to conservative excision or upper vaginectomy, which is performed in conjunction with radical hysterectomy for patients

with an intact uterus. Bilateral pelvic lymph node dissection is required, given the extensive lymphatic network of the vagina and the risk of occult nodal spread. Surgical series have reported rates of pathologic nodal involvement that range from 6% to 14% for stage I disease and from 26% to 32% for stage II disease. For distal vaginal lesions, the surgical approach involves total vaginectomy, or vulvovaginectomy, and inguinofemoral lymph node dissection. Anterior, posterior, or total exenteration is performed less commonly for early-stage disease, as radiation therapy is the preferred modality for organ preservation.

Surgical series have reported 5-year survival rates ranging from 53% to 92% for women with early-stage disease who were treated with conservative excision or partial or total vaginectomy. These reports show a survival advantage for surgery over definitive radiotherapy, although selection bias is inherent, as patients with larger tumors and comorbid disease were less likely to be surgical candidates. In a study from the National Cancer Data Base, the 5-year survival rate was 90% for women with stage I disease who were treated with surgery alone, compared with 63% for those who received definitive radiotherapy. Similar results from a Surveillance, Epidemiology, and End Results analysis found an increased risk of mortality among stage I patients who received definitive radiotherapy compared with those who were treated surgically, with an adjusted hazard ratio of 1.5. Survival outcomes for stage II disease also favor surgery in these population-based studies, although the difference is not statistically significant. However, patients with stage II disease are more likely to require total vaginectomy or an exenterative procedure to obtain negative surgical margins. Laparoscopic radical vaginectomy with the construction of a neovagina has been proposed as an organ-sparing surgical alternative. Neoadjuvant chemotherapy has also been used as a downstaging method prior to radical surgery. In a study of 11 patients with FIGO stage II disease who were treated with 3 cycles of neoadjuvant cisplatin and paclitaxel prior to radical vaginectomy and pelvic lymphadenectomy, complete and partial clinical response rates were 27% and 64%, respectively, and 73% were disease-free at the last follow-up. In patients with an incomplete resection or pathologically involved lymph nodes, adjuvant radiotherapy is delivered with 5-year survival rates of 100% for stage I disease and 40% to 69% for stage II disease (see Variant 2, above).

Large, institutional series of definitive radiotherapy for early-stage vaginal cancer have reported 5-year cause-specific survival rates of 40% to 92% for stage I disease and 35% to 78% for stage II disease (see Appendix 1 in the original guideline document). In patients with superficial stage I lesions, brachytherapy alone has been used with 5-year survival rates of 53% to 100%. Pelvic failure rates following brachytherapy alone range from 14% to 33%. Although several studies have shown no difference in outcome from adding external beam radiation therapy (EBRT) to brachytherapy for stage I disease, others have advocated for using that combination in patients with higher grade and infiltrative lesions, given the increased risk of local-regional failure. In stage II disease, the combination of EBRT and brachytherapy has been associated with improved pelvic control and survival. The predominant pattern of failure following definitive radiotherapy is locoregional, similar to that of surgery.

Treatment of Locally Advanced Disease

Advanced-stage vaginal cancer is primarily managed with definitive radiation therapy with cause-specific survival rates that range from 23% to 59% for stage III disease and from 0% to 25% for stage IV disease (see Appendix 1 in the original guideline document). Corresponding pelvic control rates are 62% to 71% and 12% to 30%, respectively. EBRT alone or in combination with intracavitary or interstitial brachytherapy has been used to deliver definitive radiation doses. In a series from MD Anderson Cancer Center, 66% of women with advanced-stage lesions were treated with EBRT alone and received lower cumulative delivered doses than those treated with a brachytherapy boost. Pelvic control and survival outcomes were not statistically different by radiation treatment modality, and 83% of relapses were locoregional. In contrast, the clinical experience from the Mallinckrodt Institute favored a combined modality approach of EBRT and intracavitary/interstitial brachytherapy for patients with locally advanced disease. The pelvic control rates for stage III disease were comparable between these large series.

Use of neoadjuvant chemotherapy prior to radical surgery has been studied in randomized trials of patients with locally advanced cervical cancer, and no detectable survival advantage was found. Case reports and small series of neoadjuvant chemotherapy for locally advanced vaginal cancer have been published, although experience is limited and most patients relapsed and died. Up front exenteration may also be considered for patients with resectable advanced-stage disease, an approach that may provide palliation in the setting of rectovaginal or vesicovaginal fistula in otherwise localized disease (see Variants 3 and 4, above).

Concurrent Chemoradiotherapy

Given the high rates of pelvic failure, the use of concurrent chemoradiotherapy has been adopted for vaginal cancer based on the survival gains observed in several randomized trials of locally advanced cervical cancer. Although there have been no prospective trials in patients with vaginal cancer, institutional reports support the feasibility of chemoradiotherapy. In a study of 14 patients with predominantly early-stage disease, radiation therapy was delivered with concurrent 5-fluorouracil (5-FU) (continuous infusion over 4 days) alone or in combination with bolus cisplatin (100 mg/m^2) or mitomycin C (10 mg/m^2). At 5 years, the cause-specific survival rate was 93%, and 1 patient had local failure. Another series that was comparable in size and composed of patients with early- and late-stage disease reported a local control rate of 92% and a 5-year progression-free survival rate of 75% with the use of concurrent weekly cisplatin (40 mg/m^2). A cohort of 26 patients with predominantly locally advanced disease was treated with definitive radiotherapy and concurrent 5-FU with or without mitomycin C or weekly single-agent cisplatin. This series reported a

5-year survival rate of 50%, and pelvic failure was documented in 31% of the patients.

Radiation Technique

EBRT for vaginal cancer is typically delivered to the pelvis with a 45 Gy dose using a 4-field or anterior-posterior-posterior-anterior (AP-PA) beam arrangement. CT simulation allows for the use of 3-D conformal treatment planning to improve target coverage and dose homogeneity, while minimizing the normal tissue dose. Conventional field borders, blocks, and multileaf collimators may be set using bony landmarks and may be adjusted based on the contoured target volume and normal tissue structures. In the absence of nodal involvement, the superior field border covers the upper extent of the external iliac lymph node region, which generally corresponds to the L5/S1 interspace. The inferior field border covers the full vaginal length. The elective nodal volume for vaginal cancer should encompass the external iliac, internal iliac, and obturator lymph nodes. If the tumor involves the superior half of the posterior vaginal wall or rectovaginal septum, the presacral and perirectal nodes are also included. For cases with distal vaginal involvement, the inguinal lymph nodes are at risk and are treated bilaterally along with the pelvic nodal groups. The gross target volume (GTV) for the primary site is defined based on physical examination findings and the local extension as identified by CT, MRI, and/or PET. The clinical target volume (CTV) for the primary tumor represents the adjacent regions at risk for microscopic spread, including the GTV with a 1–2 cm margin, full vaginal length, and paravaginal tissues.

An additional boost dose may be delivered to the primary site or the involved lymph nodes using a 3-D conformal technique or intensity-modulated radiation therapy (IMRT). The use of IMRT for vaginal cancer has not been evaluated, and, if used, tumor regression and movement of the vagina with organ filling should be considered in the planning process, as the vaginal apex may be displaced by 1.5 to 2 cm on average in the AP direction. In patients with locally advanced disease treated with EBRT alone, a parametrial or nodal boost is frequently delivered to the pelvic side wall or involved lymph node(s) to a cumulative dose of 55 to 66 Gy, whereas the primary tumor receives approximately 64 to 70 Gy. Due to limited published data, the use of stereotactic body radiotherapy (SBRT) for treating gynecologic malignancies is considered investigational.

Brachytherapy

The choice of the brachytherapy modality is based on the residual tumor thickness following pelvic radiation therapy. Vaginal cylinder brachytherapy is appropriate for residual disease measuring <5 mm in thickness, whereas interstitial implants are performed for bulky residual tumors. The most common brachytherapy modalities used in clinical practice are low-dose-rate (LDR), high-dose-rate (HDR), and pulsed-dose-rate delivery. HDR and LDR intracavitary brachytherapy have comparable local control, survival, and complication rates. For cylinder brachytherapy, the full vaginal length typically receives a cumulative dose of 60 to 65 Gy, while the region of the tumor is boosted an additional 10 to 20 Gy. For interstitial brachytherapy, the cumulative delivered dose ranges from 70 to 85 Gy, and the recommended dose schedules are described elsewhere. For treatment planning based on 3-D, simulation with MRI or fusion of MR images with CT simulation at the time of interstitial brachytherapy has been reported with favorable outcomes. For CT-based planning, the placement of fiducial markers may be used to demarcate the superior, inferior, and lateral extent of the tumor for contouring purposes.

Treatment Considerations

As in cervical cancer, retrospective studies have identified a prolonged overall treatment time and lower hemoglobin level as treatment-related factors associated with poor survival for vaginal cancer. The American College of Radiology (ACR) consensus panel recommends the completion of definitive radiotherapy within 8 to 9 weeks and transfusion as needed to maintain hemoglobin levels of >10–11 gm/dL to promote tumor oxygenation. Individual management decisions for vaginal cancer are based on the patient's extent of disease, the presence of comorbid illness, and the desire to maintain ovarian and/or sexual function. In patients with metastatic disease or poor functional status, palliative radiotherapy may play an important role in alleviating the pain and bleeding associated with uncontrolled pelvic disease.

Follow-up

The standard follow-up for vaginal cancer involves a clinical examination every 3 months for 2 years, then less frequent intervals thereafter. Based on the practice for locally advanced cervical cancer, consideration of posttreatment PET/CT surveillance is reasonable for patients with initial bulky disease.

Summary

- Due to the rarity of vaginal cancer, treatment recommendations are extrapolated from single institutional reports and prospective studies of cervical and anal cancer.
- Advanced imaging modalities, such as MRI and PET/CT, may be used to delineate the tumor size and extent, evaluate nodal or distant metastatic spread, and perform post-treatment surveillance.
- For early-stage disease, surgery or definitive radiotherapy results in similar outcomes, although EBRT and brachytherapy are preferred for organ preservation.

- The addition of concurrent weekly cisplatin should be considered for all patients with advanced-stage disease and for the majority of patients with early-stage disease.
- When available, cylinder or interstitial brachytherapy is the preferred modality to deliver an additional boost dose to the primary tumor.
- In patients with metastatic disease, bleeding and/or pain palliation may be achieved with a hypofractionated radiation course.

Abbreviations

- 2-D, 2-dimensional
- 3-D, 3-dimensional
- 5-FU, 5-fluorouracil
- BID, twice a day
- CT, computed tomography
- CTV, clinical target volume
- EBRT, external beam radiation therapy
- FDG, 18-fluoro-deoxyglucose
- FIGO, Federation of Gynecology and Obstetrics
- IMRT, intensity-modulated radiation therapy
- MRI, magnetic resonance imaging
- PET, positron emission tomography
- RT, radiation therapy
- SCC, squamous cell carcinoma
- SI, sacroiliac

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Vaginal cancer

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Oncology

Radiation Oncology

Radiology

Surgery

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic examinations and treatment procedures for management of vaginal cancer

Target Population

Patients with vaginal cancer

Interventions and Practices Considered

1. Pretreatment evaluation
    - X-ray chest
    - Computed tomography (CT)
        - Abdomen and pelvis
        - Chest
    - Magnetic resonance imaging (MRI) abdomen and pelvis
    - 18-Fluoro-deoxyglucose positron emission tomography (FDG-PET)/CT whole body
    - Cystoscopy
2. Definitive treatment
    - Upper vaginectomy and pelvic node dissection
    - Brachytherapy alone
    - External beam radiation therapy (EBRT) alone
    - EBRT and brachytherapy
    - Local excision and EBRT
    - Chemoradiotherapy
        - EBRT alone
        - EBRT and brachytherapy
    - Vulvovaginectomy with anterior exenteration
    - Neoadjuvant chemotherapy
        - Followed by radiation therapy (RT)
        - Followed by radical surgery
    - Exenteration with postoperative for close/positive margins
    - Palliative RT
3. Concurrent chemotherapy
4. Primary management
    - Palliative radiotherapy
    - Palliative chemotherapy
    - Chemoradiotherapy
    - Palliative exenteration
    - Best supportive care with pain management
5. Brachytherapy technique (vaginal cylinder or interstitial implant)
6. Brachytherapy modality (low-dose-rate, high-dose-rate, pulsed-dose-rate)

7. Radiation therapy techniques
8. Elective nodal coverage
9. Superior field border (nodal clinical target volume)
10. Method of boost (3-dimensional conformal, intensity modulated RT [IMRT], cylinder brachytherapy, interstitial brachytherapy)
11. Cumulative delivered dose
12. Radiation fields and radiation dose

Major Outcomes Considered

- Utility of radiologic procedures for pretreatment evaluation and staging of vaginal cancer
- Survival rates (5-year, disease-specific, overall, disease-free)
- Pelvic control rates/pelvic failure rates
- Response rates (complete clinical, partial clinical)

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff will search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is

circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic examinations and treatment procedures (radiation therapy, chemotherapy, and surgery) for the management of vaginal cancer

Potential Harms

Risk of radiation-associated malignancy

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists,

radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Radiation Oncology–Gynecology

Composition of Group That Authored the Guideline

Panel Members: Larissa J. Lee, MD (*Principal Author*); Anuja Jhingran, MD (*Co-author*); Elizabeth Kidd, MD (*Co-author*); David K. Gaffney, MD, PhD (*Co-author and Panel Chair*); Higinia Rosa Cardenes, MD, PhD (*Panel Vice-chair*); Mohamed A. Elshaikh, MD; Beth Erickson, MD; Nina A. Mayr, MD; David Moore, MD; Ajmel A. Puthawala, MD; Gautam G. Rao, MD; William Small Jr, MD; Mahesh A. Varia, MD; Andrew O. Wahl, MD; Aaron H. Wolfson, MD; Catheryn M. Yashar, MD; William Yuh, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – therapeutic studies. Reston (VA): American College of Radiology; 2013 Nov. 4 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria® management of vaginal cancer. Evidence table. Reston (VA): American College of Radiology; 2013. 24 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

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